

EXHIBIT 2



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

April 4, 2005

FILE COPY

Mr. Peter O. Safir
Covington and Burling
1201 Pennsylvania Avenue, N.W.
P.O. Box 7566
Washington, D.C. 20004-2401

Dear Mr. Safir:

Your petition requesting the Food and Drug Administration to refuse to approve abbreviated new drug applications (ANDAs) referencing Arava (leflunomide) tablets, was received by this office on 03/31/2005. It was assigned docket number 2005P-0127/CP 1 and it was filed on 04/01/2005. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

A handwritten signature in black ink, which appears to read "Lyle D. Jaffe", is written over the typed name.

Lyle D. Jaffe
Division of Dockets Management
Office of Management Programs
Office of Management